# Open Up the Future





# Mitsubishi Tanabe Pharma's Value Creation Model

# We contribute to the healthier lives of people around the world through the creation of pharmaceuticals.

Mitsubishi Tanabe Pharma was established in October 2007. To contribute to the health of people around the world, we will continue our effort of opening up the future of medical care.

> **Business/** Strategy  $\rightarrow P.07$

# Strategy

Medium-Term Management Plan 16-20

# Open Up

Maximizing Pipeline Value Strategic priority 2:

Strengthening IKUYAKU and Marketing

# **Business processes**



# The Basis of Value Creation

- Diversified human resources
- Compliance
- Corporate governance

# Strengths

# $\rightarrow P.03$

- Drug discovery capabilities/ Drug fostering and evolution capabilities
- Trust of patients and medical professionals
- DNA to take on challenges and change
- Core value chain as a traditional pharmaceutical company

# Pharmaceuticals and healthcare

- services with differentiated value
- Reliable products and sustainable supply
- Appropriate use of products

Materiality  $\rightarrow P.05$ 

- Ethics, fairness and sincerity in business practices
- Stakeholder engagement
- Employee health, diversity and inclusion
- Social contribution activities for health

# Risk

- Increasing incidence rate for adult-onset diseases and rising mortality
- Increasing risk of failing health insurance systems
- Growing forays into the medical and healthcare fields from other industries

Consideration

Contributing to the healthier lives of people around the world

Related SDGs  $\rightarrow P.06$ 

Providing Value to Society  $\rightarrow P.09$ 

3 GOOD HEALTH AND WELL-BEING

Extension of healthy life expectancy

Approach to Value Creation → P.08

# Development pipeline

to be the first to deliver original value

# Modality and digital changes

that contribute to new medical needs

# Raise the QOL of patients and their families

Contribute to QOL, which is to say, raise the quality of their life and living

# Raise society's productivity

Contribute to increasing social productivity by providing superior pharmaceuticals and medical care services

# Prevent disease

Contribute to maintaining people's health through vaccines that prevent infectious diseases and medical care to prevent the deterioration of patients' conditions

# 8 DECENT WORK AND ECONOMIC GROWTH









# the Future"

Strategic priority 3:

Accelerating U.S. Business Development

Strategic priority 4:

Reforming Operational Productivity

## Four priority disease areas

- Immuno-inflammation
- Diabetes and kidney
- Central nervous system
- Vaccines

#### **Opportunities**

- Expand market for health information services (shift from treatment to prevention)
- Realize unmet medical needs
- Progress in digitizing medical and health information using ICT

#### Main Stakeholders

- Patients and their families
- Healthcare professionals
- Shareholders and investors
- Employees
- Business partners
- Local communities

# Strengths

# Mitsubishi Tanabe Pharma's strengths backed by its achievements

The MTPC Group's strong drug discovery and drug fostering and evolution capabilities have resulted in the creation of many innovative pharmaceuticals.

Underpinning this are the relationships of trust with its stakeholders.

We will continue to provide society with new value based on our DNA to challenge and change backed by our more than 300 years of history.

- Drug discovery capabilities / Drug fostering and evolution capabilities
- 2. Trust of patients and medical professionals
- 3. DNA to take on challenges and change
- 4. Core value chain as a traditional pharmaceutical company

# Imusera (Gilenya)

This drug has contributed to the treatment of MS in more than 80 countries and regions as the world's first oral MS treatment agent that is an alternative to injections.



# Radicava (Radicut)

Radicava is the first new drug in nearly 20 years in the U.S. that limits the progress of ALS and helps improve patients' QOL.



# Tenelia, Canaglu (Invokana), Canalia

We have contributed to diabetes treatment with the addition of two medicines created in-house with completely different mechanisms of action and the first combination tablets in Japan.



#### Remicade

Remicade is the first antibody in Japan with 13 indications, including rheumatoid arthritis, that contributes to the treatment of a wide range of diseases.





# Materiality

In accordance with the corporate philosophy of "contributing to the healthier lives of people around the world through the creation of pharmaceuticals," the Mitsubishi Tanabe Pharma Group believes that its ability to survive and grow depends on the provision of social value and a contribution to the achievement of a sustainable society through the Group's business activities. To clarify that idea and reinforce our initiatives, we have designated material issues that we need to address as materiality and set monitoring indicators for each of them.

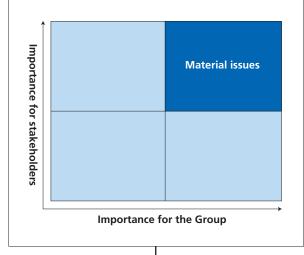
# **Process of designating material issues**

# Identify social issues that need to be considered

In designating material issues, the Group considered international guidelines as well as GRI standards, among others. In this way, social issues that need to be considered were identified in a comprehensive manner.

#### **Prioritize social issues**

For social issues that were identified, we created a materiality map that was analyzed and organized along two axes based on 1) importance for the Group, and 2) importance for stakeholders, and we narrowed down the items that were high priority.



# Confirm appropriateness and designate material issues

We designated the material issues after the validity of the materiality map was confirmed through consultation with experts from inside and outside the Company.

# Material issues / Major initiatives / Monitoring indicators

Material issues / Major ini	tiatives / Monitoring indicators
Material issues	Major initiatives
1) Pharmaceuticals and healthcare services with differentiated value	Creating new drugs, adding indications, changing dosage and administration, adding formulations, and improving products.
2) Reliable products and sustainable supply	Building systems for a sustainable supply of reliable pharmaceuticals.
3) Appropriate use of products	Establishing a drug consultation center, collecting safety information, and providing information related to the appropriate use of products.
4) Ethics, fairness and sincerity in business practices	Working to cultivate an awareness of compliance issues, establishing and observing a variety of policies, and establishing hotlines related to compliance and harassment.
5) Stakeholder engagement	Implementing timely, appropriate information disclosure, implementing dialogue with stakeholders including investors and employees.
6) Employee health, diversity and inclusion	Taking steps to establish a work environment that enables all employees to participate actively, including promotion of health management; maternity leave, childcare leave, and nursing-care leave; and initiatives for LGBT employees.
7) Social contribution activities for health	Providing support for patient organizations and research, providing information related to diseases, the provision of vaccines in developing countries, and the GHIT Fund.

# WEB

Please refer to URL below for information about KAITEKI. https://www.mitsubishichem-hd.co.jp/english/kaiteki\_management/kaiteki/



	Monitoring indicators	Fiscal 2018 results (scope of calculation)	Related SDGs	Related KAITEKI MOS indictors <sup>1</sup>	
	Number of approvals (last 5 years)	23 (Global)			
	Number of product improvements (last 5 years)	13 (Global)	3 GOOD HEALTH 9 MOUSTRY, INVOVATION AND WELL-BEING	H-1 Contribute to medical treatment H-2	
	Awards received for drug discovery (total since 2007 merger)	18 (Global)	AND WELL-BEING AND INFRASTRUCTURE		
	Number of vaccines shipped	17 million (Japan)		Contribute to the prevention and early	
	Number of patients using orphan drugs <sup>2</sup> provided by MTPC	100,000 (Global)		detection of diseases	
	The rate of complaints attributed to manufacturing process at group manufacturing plants	1ppm³ (Global)	3 GOOD HEALTH 12 RESPONSIBLE CONSUMPTION AND PRODUCTION	C-1 Endeavor to earn greater	
	Satisfaction rating of responses to customer complaints	92.4% (Japan)	-W <b>*</b> CO	recognition of corporate trust from society	
	Number of external presentations on clinical research (papers / academic conferences, etc.)	56 (Global)	3 GOOD HEALTH 12 RESPONSELE CONSUMPTION AND PRODUCTION	C-1 Endeavor to earn greater	
	Instances of safety information collected by MRs	7,419 (Japan)	<i>-</i> ₩ <b>•</b> CO	recognition of corporate trust from society	
	Compliance training participation rate	97.7% (Japan)	12 PESPONSBUE CONSUMPTION AND PRODUCTION TO SENTENCES INSTITUTIONS INSTITUTIONS	C-1 Endeavor to earn greater	
	Employee compliance awareness (Perfect score: 5 points)	4.34 points (Japan)		recognition of corporate trust from society	
	Number of briefings and interviews of investors	198 (Global)		C-2 Promote communication	
	<ul> <li>Employee understanding of management (Perfect score: 5 points)</li> </ul>	3.68 points (Japan)	12 RESPONSBLE CONSUMPTION AND PRODUCTION		
	Number of next-generation educational support activities (visiting lectures, company visits, etc.)	10 (Japan)	CO	and work in concert with stakeholders	
	Total working hours (per employee, per month)	153.9 hours (Japan)			
	Usage rate of paid vacation days	68% (Japan)	3 GOOD HEALTH 5 GENDER EQUALITY		
	Smoking rate	19.8% (Japan)	-₩ <b>* \$</b>	C-2 Promote communication	
	Employee awareness of diversity (Perfect score: 5 points)	3.72 points (Japan)	8 DECENT WORK AND ECONOMIC GROWTH	and work in concert with stakeholders	
	Percentage of women in managerial positions	20.2% (Global)			
	Number of employee nationalities	29 (Global)			
	Number of visitors to health support websites	7.29 million (Global)			
	Rate of employee participation in social contribution activities	42.3% (Japan)	3 GOOD HEALTH 9 MOUSTRY ENGVIATOR AND WELL-BEING		
	Number of organizations supported by Tenohira Partnership Program (total since start of grant in FY2013)	91 (Japan)	-W∳ 17 PATRICIONES  CONTRACTOR COMMON CONTRACTOR COMMON CONTRACTOR COMMON CONTRACTOR COMMON CONTRACTOR CONTRA	C-2 Promote communication and work in concert with stakeholders	
	Number of supports provided by health contributing programs in developing countries	12,236 meals (Japan) vaccine 14,500 doses (Japan)			

MOS indicator: Management of Sustainability (MOS) A management method unique to Mitsubishi Chemical Holdings
 Orphan drug: Medicines for diseases that are said to be intractable disease for which there are few patients and for which no cure has been established
 1ppm=0.0001%

# **Business/Strategy**

# Overview of Medium-Term Management Plan 16–20

# Open Up the Future

The operating environment in the pharmaceutical industry is undergoing dramatic change.

In this setting, we must steer our own course and implement reforms to become
a "company that works with a sense of speed and is the first to deliver differentiated value."

# Four strategic priorities to Open Up the Future



### Three growth drivers

	Features/Appeal	Goal/Strategy	
MT-1186 Radicava oral suspension	<ul> <li>Development of suspension agent that is easy for ALS patients to take</li> <li>Eliminates extended treatment time resulting from intravenous infusion administration</li> <li>Eliminates limits on number of administration sites</li> </ul>	Development plan under discussion with U.S. FDA with expected launch in fiscal 2021. Along with existing IV infusion preparations, our aim is for sales of ¥70–100 billion at peak.	
MT-2271 Seasonal influenza Plant-based VLP° vaccine	Shorter time for manufacture     Matches circulating strains (no egg adaptation)	Goal is fiscal 2021 launch. Anticipating market growth based on increasing demand for non-egg-based vaccines, with peak sales target of ¥40–60 billion.	
ND0612	Continuous subcutaneous injection stabilizes levodopa concentration in blood and improves time of onset of motor complications in Parkinson's disease patients	Aiming for fiscal 2022 launch. The product combines device and pharmaceutical with high barriers to entry for other companies, and we expect market value to be maintained. Aiming for sales of ¥50–80 billion at peak.	

<sup>\*</sup> Acronym for "virus-like particle." It is expected that a safe vaccine that is theoretically free of infection can be produced by leveraging the properties of VLP.

# Approach to Value Creation

# Main development pipeline

## MT-1303 (amiselimod)

Concluded licensing agreement (April 2019)

- MTPC grants Bausch Health Companies exclusive rights to develop and commercialize MT-1303 worldwide, except for Japan and certain other countries in Asia, in all fields, excluding neurology, rheumatology and certain rare dermatology diseases.
- Salix Pharmaceuticals Bausch Health Companies a wholly owned subsidiary of Bausch Health Companies plans to begin global development of MT-1303 with the added indication of ulcerative colitis.

**Future MTPC Initiatives** 

- MTPC will file applications for approval and sales in its territories using clinical data provided by Salix Pharmaceuticals.
- MTPC will conduct global in-house development in disease areas such as neurology and rheumatology.

## Items targeted for late-stage development

Item	Target disease Unmet medical needs <sup>1</sup>		Planned for fiscal 2019
MT-8554	Vasomotor symptoms	Safety issues have been reported with hormone replacement therapy and an effective and safe agent is desired.	Phase 2 study completed Under consultation with FDA for Phase 3 study
MT-3995	Non-alcoholic steatohepatitis (NASH)	A multifaceted disease that may eventually lead to cirrhosis and liver cancer, but no therapeutic agents exist.	PoC <sup>2</sup> study results to be obtained in Q2 FY2019
MT-7117 <sup>8</sup>	Erythropoietic Neither standard treatment nor oral drug candidate has been developed in US. The only prevention is to avoid exposure to sunlight.		PoC study results to be obtained in Q3 FY 2019

- 1. Medical needs for which there are no effective treatments or drugs
- 2. Acronym for Proof of Concept. Confirmation of the efficacy and safety of new drug candidate substances in humans at the R&D stage

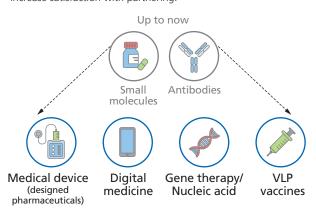
#### 3. Fast track designated by the FDA

# Modality and digital changes

We will search for drug discovery targets by analyzing medical needs based on the pathway to treatment (patient journey), from diagnosis of disease to treatment period and on to prognosis. To deliver new pharmaceuticals and medical services with differentiated value as fast as possible, we will acquire new modalities in collaboration with partners and streamline clinical trial design by using AI.

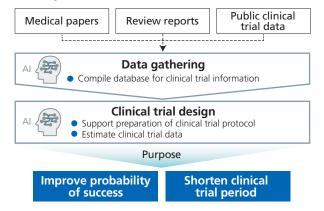
# Using modalities

In addition to conventional small molecules and antibodies, we also focus on a wide range of modalities. New modalities rapidly increase satisfaction with partnering.



# **Using AI**

We are streamlining clinical development by combining AI that supports information/data collection with AI that supports clinical trial design.





# Achieving a healthy and sustainable society through medical care

In Japan and other developed countries, social security spending has increased dramatically due to the rapid aging of the population and declining birthrates, so a balance between reducing medical costs and providing high-quality medical care is needed. The key to solving this issue is to extend the healthy life expectancy of people, in other words, extend the period that people can live without their daily lives being restricted by health problems.

The Group will not only improve the QOL of patients and their families by providing pharmaceuticals and medical services that meet unmet medical needs, it will also contribute to raising society's productivity by increasing the number of people who can work in good health.

Furthermore, the Group will help to prevent disease by providing vaccines that prevent infectious diseases and medical care that prevents the deterioration of the patient's condition.

We seek to achieve a sustainable society by extending the healthy life expectancy of people through the dissemination of these values.

⇒ Please see "Message from the President" on page 11 for details.



# Provide value to society

# Extend healthy life expectancy

Raise the QOL of patients and their families

Raise society's productivity

**Prevent disease** 

Achieve a healthy and sustainable society

# Main contribution examples

## Imusera (Gilenya)

The world's first oral treatment agent for multiple sclerosis that reduces the mental and physical burden of injections. It also contributes to the improvement of patients' QOL.

#### Radicava (Radicut)

A treatment agent for ALS, a rare disease. It has been approved and launched as a new drug for the first time in 20 years in the U.S. and contributes to the treatment of patients.

#### Remicade

As the first antibody in Japan, it controls the progress of joint destruction and pain in patients caused by rheumatism, and supports their lives.

#### MT-2271 (Drug candidate)

VLP vaccine for seasonal influenza. Its manufacturing time can be reduced compared with conventional egg-based vaccines.

#### ND0612 (Drug candidate)

It was designed to reduce the burden of everyday life during treatment by combining a medical device with the treatment of Parkinson's disease.



1

# Long-term vision for our management direction

### Question:

What value does the Company provide to society?

#### Answer:

Mitsubishi Tanabe Pharma benefits society by providing treatments and preventive medicines that contribute to extending healthy life expectancy.

The rapidly aging demographics of Japan and other developed nations is leading to a crisis point for the sustainability of social security systems. I believe that this makes it incumbent for pharmaceutical companies like ours to step up and contribute to society by creating pharmaceutical products and medical services that provide higher medical value while lowering medical costs.

The Mitsubishi Tanabe Pharma Group has always considered it to be important not just for people to live long lives, but to live long and healthy lives of comfort and joy. We believe pharmaceutical companies contribute to extending healthy life expectancy in three ways. The first is to help raise the quality of life by helping treat illnesses so patients can lead productive lives. Another is to contribute to the productivity of society by increasing the number of people working with their full energy. And the final way is to stop illness before it strikes or, in a word, provide "prevention." I believe that the products and services we offer contribute in all three of these ways and truly help people live long and healthy lives.

Remicade is an example of one of our products that helps raise the quality of life of patients and lifts the productivity of society. Remicade is the world's first monoclonal antibody preparation against TNF-alpha, while it has also exhibited positive results for various indications. Rheumatoid arthritis is becoming increasingly common as populations age, and in Japan some 700,000-800,000 people are suffering from the inflammatory disorder. The symptoms include intense joint pain and ultimately damaged joints to the degree that regular daily activities become difficult and painful. Although there is currently no cure for rheumatoid arthritis, Remicade is able to provide relief for many patients. A doctor once told me about its effects: "Remicade enabled an elderly farmer to be able to take care of her grandchild so her son and his wife could work the fields. It helped their whole family situation." So medicine

we developed not only relieved one person's pain, it was also a catalyst for others to become more active and participate in the labor force. On a larger scale, I could see that medicine can have a big impact on local communities and could even bring smiles to people's faces.

Another area where we are particularly active is developing preventive medicines, particularly vaccines. The MTPC is one of just a handful of Japanese entities that is working in all aspects from R&D through to marketing to develop vaccines with the Research Foundation for Microbial Diseases of Osaka University. We are also developing drugs for other forms of preventive treatments. Recently, clinical trials overseas found that the canagliflozin treatment (marketed as Canaglu in Japan and Invokana in the U.S.) for type 2 diabetes helps inhibit the lifestyle disease from progressing to diabetic nephropathy (diabetic kidney disease). Canagliflozin treatment therefore shows promise for blocking diabetes from progressing into nephropathy and inhibiting the development of further complications.

Living a healthy life requires more than taking care of the body. It also means taking care of the mental aspects, such as maintaining positive relations with family members and the local community. A person who is living a healthy life is active, has a positive outlook, and enjoys doing their work. Increasing the number of people living healthy lives contributes to maintaining and raising the productivity of society as a whole.

Prevention is also essential to reducing the number of people who come down with illness. In that sense, I believe our business helps individual patients but it can also contribute to resolving wider social issues.

Medicine is an accumulation of knowledge. As a business, it's not the power of capital but the quality of a pharmaceuticals company's patents that makes it competitive with large companies overseas. Capital might does not determine success in the pharmaceuticals industry, nor does R&D or manufacturing capability. The key to success is the capabilities of a company's people and the expertise they bring to the production site. That is why Japan is one of only a handful of countries in the world that can produce innovative medicines.

Japan's pharmaceutical industry is going through a challenging period, and I believe we have a responsibility to transform our company so future generations can fulfill our important mission.

# Message from the President

2

Strengths, risks, and opportunities

### Question:

What are the company strengths that will drive its long-term growth?

#### Answer:

# One strength is our historically proven ability to transform ourselves.

Our predecessor, Tanabe Seiyaku, was established over 300 years ago, and I believe the key to our longevity has been the ability to undergo not just one but several major transformations.

Tanabe Seiyaku originally specialized in natural remedies like Chinese herbal *kanpo* medicine but in the 1870s began offering new western medicines imported from Germany and in 1925 started mass-producing and marketing a product (salicylic acid) formulated from organic compounds. In short, the Company transformed from wholesaler of herbal medicines to a modern company offering manufactured products.

In 1974, the Company achieved its first global product through out-licensing of the hypertension treatment diltiazem (product name: Herbesser), which transformed the Company again, this time from a domestic business to a global operation. Our latest major transformation came when Tanabe Seiyaku merged with Mitsubishi Pharma Corporation in 2007. The history of our evolution makes me believe that the Group is ready for another major transformation.



I believe we need a transformation now because we are entering a whole new era with unprecedented challenges that will require the entire pharmaceutical industry in Japan to change. The government's policy to promote generic drugs has made it very difficult for pharmaceutical makers to increase profits on drugs with expired patents. On top of this economic reason, scientific advances like the advent of extremely low-cost analytic technologies, such as for the previously costly genome sequencing, and the rapid advances in digital technology, including in IoT and AI, are also compelling an industry-wide transformation.

In these conditions, whether or not we can realize our next transformation will influence the future course of the Company. In fact, we strongly feel that failing to transform the Company now will lead us to a crisis point not 30 years from now, but in just 10 years.

Transformation requires innovation. I am focusing on stimulating innovation by combining medical and digital technologies to create new hybrid medical devices. In areas where chemical expertise alone is not enough to differentiate pharmaceutical products, I believe there will be increasing opportunities to also use physic and engineering technologies, such as our devices and digital technology, to create solutions.

Consolidating our R&D bases and moving into the Shonan Health Innovation Park are two steps we have taken to stimulate innovation. The main objective of these moves is to be in contact with and integrate the latest developments arising from the explosive fusion of the computer and life sciences. We will proactively enter the open innovation space, seek promising partnerships, and form collaborations to create innovation for the medium- and long-term horizon. The pursuit of innovation will also require an internal transformation in our researchers. By expanding their sphere of contact outside traditional boundaries, our presence at the new facility will give them opportunities to broaden their perspectives.

# Answer:

# Another important strength is our corporate culture emphasizing trust and a desire for progress.

The core value chain for fundamental drug discovery that the Group has developed in its traditional business as a pharmaceutical company is another strength. Our drug discovery capabilities have garnered numerous awards from third-party institutions and I often receive comments that our manufacturing expertise and sales capabilities are straightforward and solid.

Upon reflection, the compliance problems we had right

after the merger are probably the reason why we are now so strong in these areas. We were adamantly determined to regain the trust that society had placed in us. Our employees should be very gratified with the results of their efforts to galvanize the whole Company to reestablish that trust. You could say that the extreme importance that we as a company place on maintaining society's trust is another of our strengths.

Another area where I think our Group stands out is the many successes we have achieved by tenaciously seeking to discover something new. For example, Remicade, which I mentioned earlier, was the first therapeutic antibody developed in Japan. We challenged ourselves to do the unprecedented: to develop an antibody drug. We didn't stop after we succeeded and marketed it. We continued our drug fostering and evolution, accumulating a growing volume of safety data and gradually adding to the indications, and it has grown into a core product with currently 13 indications.

We have also led the industry in developing drugs for incurable and rare diseases, including the Imusera (overseas: Gilenya) treatment agents for multiple sclerosis and the Radicava (in the U.S.: Radicut) treatment agent for amyotrophic lateral sclerosis (ALS). This desire to do something nobody else has done before and then to carefully see it through to the final result is in our Group's DNA.

### Question:

What particularly promising opportunities does the Company see ahead?

#### Answer:

We believe the combination of the life sciences and digital technologies will bring major business opportunities.

As I mentioned earlier, the sharp drop in medical research costs, such as for genome sequencing, and the advances in IoT, AI, and other technologies are accelerating the integration of the life sciences and digital technology.

This fusion is behind remarkable advances in cancer treatments, and the Group wants to use it to advance treatments of immuno-inflammation. As with cancer, the effectiveness of the treatment agents changes depending on each patient's individual genetics. We believe these precision medicines whose effectiveness relies on genetic response offer a huge business opportunity. The Digital Transformation Department has been given the mission to revamp our overall business flow and also to identify and develop new business opportunities in the precision medicine field.

### Question:

What major risks do you see?

#### Answer:

Patent expirations on new drugs present risk, but we are countering by expanding our long-tail businesses.

The new drug business carries the risk of patent cliffs, a plummet in revenue when their patents expire. We are mitigating this risk by increasing the portfolio ratio of long-tail businesses that do not rely on patents and have the potential to generate continuous revenue.

A business combining drug and a device can be a long-tail business. Insulin delivery devices are a classic example. Even after a drug patent expires, companies that market these are largely protected from competition by the barrier to developing a device, plus they generate repeat business from the need to renew the devices. Vaccines that do not have a generic alternative are another type of long-tail business. We plan to increase our weighting of drugs with devices, vaccines, and other long-tail businesses to establish a more stable revenue base.



Addressing ESG challenges

### Question:

What is the Company's approach to ESG?

#### Answer:

We have specified seven material issues to address through our businesses.

The Group recognizes that fortifying its ESG activities is essential to its long-term growth. In fiscal 2018, we identified specific material issues (important social issues) based on the Sustainable Development Goals (SDGs) of the United Nations and the international guidelines of the Global Reporting Initiative (GRI) that we will focus on addressing with our businesses. In fiscal 2019, we instituted monitoring indicators that will enable management and outside entities to visually track the progress of our ESG initiatives.

Of the seven material issues, the one that we are particularly emphasizing as a pharmaceutical manufacturer is "pharmaceuticals and healthcare services with differentiated value." To become a company that can provide original value at all stages from disease

# Message from the President

prevention to diagnosis, treatment, and post-treatment recovery, we plan to actively develop the pharmaceutical products in our core businesses while also offering devices and medical services as we pursue various channels to contribute to extending healthy life expectancy for people around the world.

We are also placing special emphasis on "employee health, diversity and inclusion." Maintaining an atmosphere of diversity and inclusion that encourages a diverse workforce to fully apply their abilities and expertise is essential to realizing innovation. Our internal resources, including our workforce and expertise, will not be enough to create new value. We are bringing together people with various skills and ways of thinking for maximum open innovation. Our hiring activities will also be geared to stimulating innovation by actively looking for people with various backgrounds and knowledge, mainly in the electronic devices and information and communications technology fields. Management also recognizes the qualitative importance of cultivating talented personnel for generational changeover and the succession of skilled expertise. We launched MT-VIVID, a management training program designed to begin early development of the next-generation of company leaders, in fiscal 2016 and are expanding our global evaluation process and training programs.

In addition to our social activities, we are also advancing environmental measures. Although the pharmaceutical manufacturing business generally has relatively less overall environmental impact, we are steadily reducing the energy consumption and CO<sub>2</sub> emissions of the Group's operations. Global warming is raising concern of an associated increase in infectious diseases, such as mosquito-borne illnesses. If infectious diseases begin to spread, the need for low-cost vaccines will also grow in all regions of the world. This has shed new light on the contribution pharmaceuticals companies that make vaccines can make to mitigating the impact of climate change, and the Group considers it to be its duty as a vaccine maker to put all our effort into developing solutions.

In the area of governance, we recognize the importance of formulating and maintaining a management structure to support our growing global business. As we prepare for full-fledged expansion of our operations in the United States, we are translating our Global Governance Policy into in multiple languages to serve our operations worldwide. We are also strengthening our compliance functions at the Group's regional headquarters in the United States, Europe, Singapore, and China. To further reinforce compliance, we plan to deeply integrate with the governance systems of each of the worldwide regional headquarters of our parent company Mitsubishi Chemical Holdings.



Short-term business conditions and outlook

#### Ouestion:

What is the status of the medium-term management plan?

# Answer:

We lowered our numerical targets, but our four strategic priorities are unchanged.

We are currently more than midway into our Medium-Term Management Plan 16–20: Open Up the Future that we launched in fiscal 2016. The plan sets four strategic priorities for growth: maximizing pipeline value, strengthening IKUYAKU (drug fostering and evolution) and marketing, accelerating U.S. business development, and reforming operational productivity. Although we remain fully committed to implementing these strategies until we achieve our target objectives, in November 2018 we revised our numerical performance targets.

The reasons for the revisions were reduced expectations

### **Revised Medium-Term Performance Targets**

(Billions of yen)

	Fiscal	Fiscal 2022	
	Initial target Revised target		Fiscal 2023
Revenue	500	430	More than 500
(of which, U.S. sales)	(80)	(40)	_
Core operating profit	100	60	More than 100



for royalty revenue, particularly from Invokana, and the slow emergence of M&A effects in the U.S. We began developing our U.S. operations with the release of the Radicava ALS treatment agent there in August 2017. However, the royalty revenues are not contributing as much to profits as we had been expecting. Also, the development of ND0612 as a treatment agent for Parkinson's disease has not progressed as we originally anticipated.

Although we revised our numerical targets, we are continuing to direct all our energies to steadily advancing the four strategic priorities. We believe that continuing to make steady progress maximizing pipeline value will lead to significant improvement in the profit contribution from the U.S. business.

# Question:

What is the business outlook and what strategies will you be implementing?

# Answer:

# We are accelerating our transformation to generate sustained growth.

The qualitative strategy is, as described above, to continue steadily advancing the medium-term management plan. As a pharmaceutical company our drug pipeline is the main driver of our business growth. We are therefore determined to successfully bring the drugs presently in the final stages of the development pipeline to market and will continue allocate a large proportion of funds to R&D. We expect this aggressive investment spending coupled with the results of arbitration proceedings with Novartis Pharma

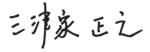
AG to result in steep declines in our core operating profit, operating profit, and profit attributable to owners of the Company in fiscal 2019.

We are presently advancing two concrete strategies to transform the Group and accelerate the attainment of sustained growth. The first is revising our product structure by employing new modalities of increased ratios of new drug and long-tail businesses. The second is transforming our business model by adding a self-distribution business structure overseas, mainly in the U.S., to our domestic and royalty businesses. We deeply regret that will need more time to reach the targets in our medium-term management plan, yet we also believe it is necessary to shore up our strength to achieve the full and most expeditious results from our strategies. We intend to emerge from this period stronger than ever.

The history of our Group includes many periods when we overcame challenges and came out stronger. I am certain that the combined effort of our management and employees will propel us to success in this new transformation of the Company.

I look forward to the understanding and support of our shareholders as we set Mitsubishi Tanabe Pharma on a new path to the future.

September 2019



Masayuki Mitsuka President & Representative Director

# Pipeline

# Status of drug candidates (as of July 25, 2019)

Asia: excluding Japan and China

Development code			_	Stag	e		
Product name	Category	Indications	Region	Phase		Origin	
(Generic name)	<b>,</b>			1 2 3	Filed		
Immuno-inflammation							
MT-5547	Fully human anti-NGF monoclonal antibody	Osteoarthritis	Japan		Phase 2/3	US: Regeneron	
MT-1303	S1P receptor functional antagonist	Multiple sclerosis	Europe			In-house	
MT-7117	Dermatologicals, etc.	Crohn's disease  Erythropoietic	Japan Global			In-house	
		protoporphyria  Endometriosis	Global				
MT-2990	Fully human anti-interleukin-33 (IL-33) monoclonal antibody	Seasonal Allergic Rhinitis	-			In-house	
Diabetes and kidney							
TA-7284 Canaglu	SGLT2 inhibitor	Type 2 diabetes mellitus	Asia			In-house	
(Canagliflozin)		Diabetic nephropathy	Japan				
MP-513 Tenelia	DPP-4 inhibitor	Type 2 diabetes mellitus	Asia China			In-house	
(Teneligliptin)	DFF-4 IIIIIIDIQI	Type 2 diabetes meiitus	Europe			III-House	
MT-6548 (Vadadustat)	Hypoxia inducible factor prolyl hydroxylase inhibitor	Renal anemia	Japan		19.07	US: Akebia	
		Diabetic nephropathy	Europe				
MT-3995	Selective mineralocorticoid receptor antagonist	Non-alcoholic	Japan			In-house	
		steatohepatitis: NASH	Japan				
Central nervous systen	n		<u> </u>	·			
MCI-186 Radicut/Radicava (Edaravone)	Free radical scavenger	Amyotrophic lateral sclerosis: ALS	China Asia		19.04	In-house	
MP-214 (Cariprazine)	Dopamine D3/D2 receptor partial agonist	Schizophrenia	Asia			Hungary: Gedeon Richter	
MT-5199	Vesicular monoamine transporter type 2 inhibitor	Tardive dyskinesia	Japan		Phase 2/3	US: Neurocrine Bioscienc	
		Painful diabetic peripheral neuropathy	Europe				
MT-8554	TRPM8 antagonist	Vasomotor symptoms associated with menopause	Global			In-house	
ND0612 (Levodopa/Carbidopa)	Continuous SC pump/ patch pump	Parkinson's disease	Global			In-house	
ND0701 (Apomorphine)	Continuous SC pump	Parkinson's disease	_			In-house	
MT-1186 (Edaravone)	Free radical scavenger	Amyotrophic lateral sclerosis: ALS/Oral suspension	_			In-house	
MT-6345	Nervous system	-	_			Japan: Co-developed with Ube Industries	
MT-3921	Anti-RGMa antibody	Spinal cord injury	_			Japan: Co-developed with Osaka Universit	

Asia: excluding Japan and China

5 1				Stage		
Development code Product name	Category	Indications	Region	Phase	Origin	
(Generic name)	J ,			1 2 3 Filed		
Vaccines						
MT-2355	Combined vaccine	Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants	Japan		Japan: Co-developed with The Research Foundation for Microbial Diseases of Osaka University	
MT-2271	Plant-based VI P vaccine	Prophylaxis of seasonal influenza/adults	US, Europe		Canada:	
1011-2271	riant-based vir vaccine	Prophylaxis of seasonal influenza/elderly	US, Europe		Medicago product	
MT-8972	Plant-based VLP vaccine	Prophylaxis of H5N1 influenza	Canada		Canada: Medicago product	
MT-7529	Plant-based VLP vaccine	Prophylaxis of H7N9 influenza	_		Canada: Medicago product	
MT-5625	Plant-based VLP vaccine	Prophylaxis of rotavirus gastroenteritis	_		Canada: Medicago product	
Others						
TAU-284 Talion (Bepotastine)	Selective histamine H1 receptor antagonist, anti-allergic agent	Allergic rhinitis, Urticaria	Asia		Japan: Licensed from Ube Industries	
MT-4129	Cardiovascular system, etc.	_	-		In-house	

# Major out-licensed products

Development code Product name (Generic name)	Category	Indications	Region	Stage Phase 1 2 3	Filed	licensee
Diabetes and kidney						
TA-7284 INVOKANA (Canagliflozin)	SGLT2 inhibitor	Diabetic nephropathy	US		19.03	US: Janssen Pharmaceuticals
Central nervous system						
MT-210	5-HT2A/Sigma 2 receptor antagonist	Schizophrenia	US, Europe			US: Minerva Neurosciences
Others						
MT-4580 Orkedia (Evocalcet)	Ca sensing receptor agonist	Hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism	Japan		19.04	Japan: Licensed to Kyowa Kirin

# A Message from an Outside Director



# Recommendations for overseas business success

In my view, the mission of an outside director is to share his opinions and recommendations after carefully examining the state of the execution of the Company's business. In that sense, as an outside director, I strive to discuss matters at the Board of Directors meeting from a wide range of viewpoints unbounded by conventional thinking and decision-making.

The major issue is not only the results of a single fiscal year, but how to advance the growth strategy from a medium- to long-term perspective, including the progress of the Medium-Term Management Plan 16–20. Given these circumstances, at the Board of Directors meeting in fiscal 2018, I paid particular attention to individual overseas businesses that are making rapid progress. The Company's overseas business is in the difficult situation of having to produce results while developing the business experience of its staff, but I want to support them as much as possible so that they succeed.

# Emphasis on the Nomination and Compensation Committees

As an outside director, I serve on the Nomination and Compensation Committees. In discussions about officer candidates in the Nomination Committee, we evaluate them giving sufficient consideration not only to a quantitative assessment, such as age and experience, but also qualitative aspects, such as the ability required for the future growth of the Company. We also discuss succession plans. In these

discussions too, I strive to express my views from an unbiased standpoint as a third party.

In the Compensation Committee, on the other hand, since the Company's compensation system is well structured, I am particularly conscious about checking how each officer's performance is reflected in their compensation.

# Efforts to live up to the shareholders' trust

While the business of "developing pharmaceuticals" itself may contribute substantially to society, we must also consider the fulfillment of social responsibilities associated with promoting business. For example, we can consider specific initiatives from the point of view of "how we can develop and produce safe products, while reducing our environmental impact as much as possible, and supply them to society."

In a corporate governance system, there is always room for governance improvement. In the future, it may be good to discuss governance not only in terms of transparency and fairness, but also in terms of what can we do to live up to the trust of shareholders. Efforts to make the Company more attractive to shareholders and investors are essential. To that end, we need to find ways to communicate information more openly.

# Corporate Governance

# Fundamental approach

The Mitsubishi Tanabe Pharma corporate philosophy is to "contribute to the healthier lives of people around the world through the creation of pharmaceuticals," and our vision is "to be a global research-driven pharmaceutical company that is trusted by society." To realize this philosophy and vision, the Mitsubishi Tanabe Pharma Group places the highest priority on fulfilling its responsibilities to all of its stakeholders, including shareholders, and working to achieve the sustainable growth of the Group and increases in its corporate value over the medium- to long-term. To that end, the Group works to ensure the transparency and objectivity of management by ensuring efficiency and promptness in management decision-making, enhancing monitoring and

supervision through the outside directors, and enhancing the auditing system through the corporate auditors.

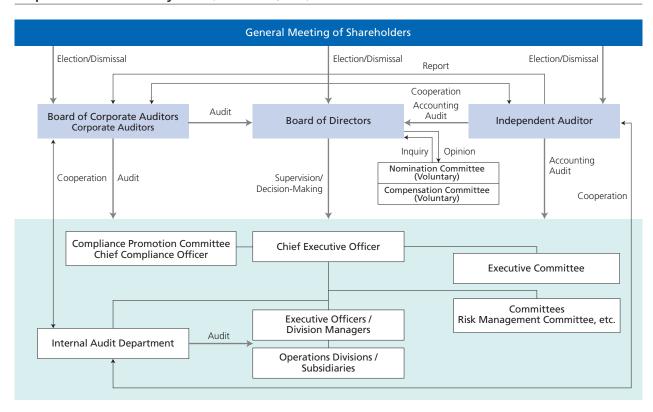
In accordance with this approach, the Group has formulated the Corporate Governance Policy of Mitsubishi Tanabe Pharma, and based on this policy the Group will continue working to realize an optimal corporate governance system.

#### WEB

The following URL provides further information about the corporate governance policy. https://www.mt-pharma.co.jp/e/company/pdf/cg\_policy\_e.pdf



# Corporate Governance System (As of June 24, 2019)



# Risk Management

# Business activity risk management

The Company has formulated Risk Management Rules and created a system for preventing risks from materializing in the overall Group's business activities, including overseas affiliates, and for minimizing loss in the event a risk does materialize.

In addition, in order to promote effective risk management, risks are managed by categorizing them according to their characteristics into "risks in management strategy," which are intrinsic to management decision-making, "material risks," which are managed across organizational units because they affect the overall Group, and "general risks," which are addressed on the responsibility of individual divisions.

The Risk Management Committee, chaired by the Chief Executive Officer, is the body responsible for overseeing and promoting risk management for the Group overall. It deliberates on and decides risk management policies, monitors risk management and makes improvements as they are needed.

As a concrete initiative for promoting risk management, the Group conducts risk assessments each year and thereby works to raise its risk sensitivity. The results are fed back to individual divisions to further reinforce risk management.

# Risk management based on risk categories

### Risks in Management Strategy

Overall category overseen by Corporate Strategic Planning Department

Examples: Risks related to M&A and alliances Risks related to new business; etc.

# **Material Risks**

(Risks Requiring Cross-Organization Management)

Risk reduction measures devised and promoted by lead management divisions

Overall category overseen by Internal Control Office

Examples: Risks related to pharmaceutical-related laws and ordinances

Risks related to large-scale disasters Risks related to information management Risks related to general laws and ordinances; etc.

### **General Risks**

(Risks Specific to Individual Divisions)

Each division devises and promotes risk reduction measures.

# Crisis management

The Group is taking measures to prepare for the possibility of a major earthquake in the Nankai Trough and an

earthquake directly under the Tokyo metropolitan area. It has revised its regulations for crisis management, including disaster response, and strengthened its system so that pharmaceuticals continue to be stably supplied to patients even in a major disaster. The Group is also working to further improve practical capabilities through business continuity, safety confirmation and communication drills and other training.

Further, the Group maintains and regularly updates manuals on tsunami, pandemics, terrorism, conflicts and other types of incidents based on the various characteristics of its sites inside and outside Japan in order to faithfully fulfill its overarching mission of providing stable supplies of pharmaceutical products.

# Information security

In order to accommodate overseas business expansion and the increasing complexity of IT infrastructure and to consistently utilize information and IT technologies, the Group is enhancing regulations and strengthening network security at overseas sites, strengthening security when using cloud services, and reinforcing its crisis management system for when security incidents occur.

# **Enhancing Global Governance**

# Megumi Ohtaki

Executive Officer, Chief Compliance Officer



With the diversity of selectable modalities in the pharmaceuticals industry further accelerating due to the advance of globalization and rapid evolution of innovative science and technology, there has been increasing uncertainty in the environment surrounding the Group's management. In such an environment, full governance globally needs to be achieved for the Group to work for sustained growth and to raise corporate value while maintaining the fairness and transparency of corporate activities and to realize its corporate philosophy, "We contribute to the healthier lives of people around the world through the creation of pharmaceuticals."

All executives and employees involved in the Group are committed to acting on the basis of the Corporate Behavior Charter while maintaining awareness of the Group's ideals. The Company intends to further enhance corporate governance to prevent information from being divided by the organizational unit or region, continue working for sustainability, and endeavor to sincerely contribute to local communities and the health of people around the world in order to thereby uphold the interests of stakeholders.

# Reliable Products and Sustainable Supply



# Quality of products

Our policy is to contribute to the health and well-being of people around the world through the stable supply of high quality, reliable products which are manufactured under a world-class quality system. On that basis, we are strictly observing the ministerial ordinance on GMP (regulations regarding pharmaceutical manufacturing control and quality control) and on GQP (regulations regarding pharmaceutical quality control). Patient safety is the first priority of every employee, and we are implementing initiatives targeting further quality assurance with a focus not only on results but also on processes. Through management, supervision, and guidance of manufacturing sites in Japan and overseas, we are working to improve the quality of the products that we provide to the market.



# Pharmaceutical manufacturing process

The Mitsubishi Tanabe Pharma Group manufactures and supplies high-quality pharmaceuticals and strictly manages

product quality from acceptance testing of raw materials procured in Japan and abroad to the manufacture of GMP-compliant pharmaceutical ingredients and preparations as well as testing and inspection, thus supplying premium quality products which patients and healthcare professionals can use safely and with peace of mind. As a global research-driven pharmaceutical company, we manufacture pharmaceuticals based on a wide range of technologies and proprietary knowhow developed over many years.

To further ensure quality, the Production Technology & Supply Chain Management Division and the Global Quality Assurance Department collaborate with the Group's manufacturing plants to develop production technologies to enhance quality, stabilize supply, and reduce costs from the early development stages of new pharmaceutical products. In addition, the Group's manufacturing plants (two in Japan and four overseas) together with manufacturing subcontractors are creating a global production system that delivers a stable supply of our products to many people around the world.

In June 2016, we built a domestic manufacturing facility within the Yoshitomi Plant for solid dosage formulations. This highly productive facility can supply pharmaceuticals in accordance with global quality standards, while further contributing to both the improvement of manufacturing technologies and the reduction of manufacturing costs.

In addition, BIKEN, a joint venture with the BIKEN Foundation's vaccine manufacturing business, began operation in September 2017. By integrating BIKEN Foundation's vaccine manufacturing technologies together with Mitsubishi Tanabe Pharma's pharmaceutical manufacturing systems and management methods, we are strengthening our platform in vaccine production in order to contribute to an even more stable supply of vaccines.



Solid dosage formulation production facility at the Yoshitomi Plant

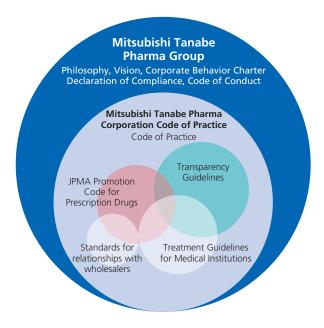
# Ethics, Fairness and Sincerity in Business Practices



# Code of Practice

The Japan Pharmaceutical Manufacturers Association (JPMA), of which Mitsubishi Tanabe Pharma is a member company, put the JPMA Code of Practice into effect in 2013. This establishes behavioral standards that must be observed by the executives and employees of the member companies in their interactions with researchers, healthcare professionals, patient organizations, wholesalers, etc. In response, the Company established and put into effect the Mitsubishi Tanabe Pharma Corporation Code of Practice. All executives and employees of the Company as well as its affiliated companies in Japan are required to follow this code not only in promotion endeavors designed for healthcare professionals, medical institutions, and others, but also in all other corporate activities, including testing and R&D, information provision activities, cooperation with patient organizations, and relationships with wholesalers. Overseas Group companies comply with the codes of each country based on the International Federation of Pharmaceutical Manufacturers and Associations' Code of Practice (IFPMA Code).

# Positioning of the Code of Practice



# Compliance training

The Group conducts the following training programs for the purpose of fostering a strong sense of ethics, raising awareness of compliance requirements, and cultivating greater awareness of compliance-related issues among all employees.

### **Groupwide compliance training**

We implement e-learning with the aim of ensuring rigorous compliance and raising human rights awareness, which are parts of the foundation of our business operations, in order to realize the corporate philosophy and vision.

# **Divisional compliance training**

We offer divisional training that focuses on specific topics relevant to each division, principally for compliance implementation personnel, including managers and staff.

#### Compliance and risk management check

Through e-learning we confirm understanding of such matters as laws, regulations, and internal rules. This enables officers and employees to act in accordance with consistent evaluation standards.

### List of training sessions held in fiscal 2018

	Times held	Number of participants
Groupwide compliance training	Once a year	5,376
Divisional compliance training	Once a year	5,385
Compliance and risk management check	Twice a year	July 2018 5,300 February 2019 5,137

## Hotlines

The Mitsubishi Tanabe Pharma Group's internal and external hotlines allow employees and managers to obtain consultation and make reports about any actual or possible violation of laws, ordinances, or social conventions. The use of the hotlines leads to the prevention or reduction of scandals, etc., before major problems develop.

In addition, reports on recent trends and issues warranting special mention are included in regular compliance training sessions, which helps promote use of the hotline and prevent recurrence.

# Number of hotline consultations handled in fiscal 2018

Workplace environ- ment	Working condition/ human resources	Embezzle- ment/ misappro- priation	Laws regulations, and rules	Other	Total
9	2	0	4	7	22

# Employee Health, Diversity and Inclusion







# Health management initiatives

In April 2016, the Group established the MTPC Group Health Policy based on its corporate philosophy, vision, and Corporate Behavior Charter and is promoting activities related to employee health effectively and appropriately.

# MTPC Group Health Policy

- We will strive to maintain our own health so that we can contribute to the health of people around the world.
- We will leverage our own capabilities and advance the establishment of an environment in which we can work energetically.

In fiscal 2018, we were recognized for the third consecutive year under the "Outstanding Enterprise in Health and Productivity Management White 500" (large enterprise category), a recognition system that is promoted by the Ministry of Economy, Trade and Industry. The Company's evaluations in the categories of "systems/policy implementation" and "evaluation/improvement" improved

from the previous year, and it has received the highest evaluation in the industry, particularly in the category of "measures and policies not limited to risk holders."



# Actively utilizing diverse human resources

The Group has positioned its approach to diversity and inclusion as one of its management strategies. We have organized that approach into the Diversity Promotion Circle, and we are advancing initiatives on that basis.

The Diversity Promotion Circle has the objective of leveraging diverse human resources and maximizing results and the Company develops those human resources to maximize the potential of diverse employees, establishes systems and frameworks that make it easy for diverse employees to do their jobs, and provides opportunities for a diverse range of people. Managers implement diversity management to draw on the capabilities of diverse employees and maximize results, and each employee generates synergies.

In regard to diversity, we take into account both visible diversity (gender, sexual orientation and gender identity (including LGBT<sup>1</sup>), age, career background, nationality, disability status, time restrictions due to childcare, nursing care, etc.) and non-visible diversity (knowledge, skills,

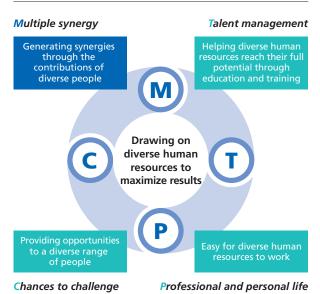
experiences, values, ways of thinking, etc.). By appreciating these differences and leveraging them, we seek to maximize our results.

In fiscal 2018, all employees undertook e-learning compliance training and departmental training based on the themes of diversity promotion and LGBT. We continued to implement nursing care seminars and www28 training (www: an abbreviation for Win-Win- Woman), which considers the careers of women who have not yet experienced such life events as marriage and childbirth. As a so-called "Ikuboss"-related measure to encourage subordinates to fulfill both work and personal matters, we fostered awareness of men's participation in childcare and child-care leave through the distribution of folded triangular shaped signs that describe the Ikuboss Declaration and holding of the Ikuboss Award to commend the company's best practices.

On the system side, we revised the rules of employment by adding harassment-related behavior and made them subject to disciplinary action. Specifically, the declaration clearly states that sexual harassment includes sexual orientation such as LGBT, discrimination and harassment based on sexual identity, and that maternity and paternity harassment<sup>2,3</sup> are also subject to disciplinary action. The declaration was widely distributed through compliance and harassment prevention guidebooks.

- 1 LGBT is an acronym for L: lesbian, G: gay, B: bisexual, T: transgender, and is a generic term for a sexual minority.
- 2 Maternity harassment is workplace discrimination against women due to pregnancy and the need to provide childcare.
- 3 Paternity harassment is workplace discrimination against fathers who have taken paternal leave to help with childcare.

# **Diversity promotion circle**



# Social Contribution Activities for Health



# The Mitsubishi Tanabe Pharma Tenohira Partner Program

The Company believes in the importance of providing support for patients with diseases and their families, and in 2012 established the Mitsubishi Tanabe Pharma Tenohira Partner Program. This program provides aid for the activities of associations and support groups for patients with intractable diseases. These organizations work to improve patients' medical treatment, education, and career prospects and to enhance their quality of life. In fiscal 2018, support was provided to 21 organizations. We established "startup grants" to support organizations that do not yet have extensive track records of activity, and have made it possible to support more organizations.

At meetings held in October 2018 to report on the fiscal 2017 activities of organizations receiving assistance under the Mitsubishi Tanabe Pharma Tenohira Partner Program (14 organizations), participants shared their opinions about challenges and solutions in conducting activities that transcend each other's diseases. The Tenohira Partner Program strives to support people fighting disease, to assist them in finding more joy and satisfaction in their lives, and to help them realize their dreams and hopes for the future. On that basis, we will continue to offer support.

In fiscal 2019, we will support nine startup grants and 10 project grants, for a total of 19 organizations.

# Participation in the Global Health Innovative Technology Fund (GHIT Fund)

The GHIT Fund aims to discover new drugs for infectious diseases that affect people in the developing world, such as malaria, tuberculosis, and neglected tropical diseases. To that end, the GHIT Fund was established as a public-private partnership from Japan. Through new drug R&D capabilities that utilize the advanced science and technology know-how of Japanese pharmaceutical companies and other institutions, the fund aims to strengthen Japan's international contribution to global health.

In May 2015, through the GHIT Fund, the Company provided its pharmaceutical compound library (50,000 compounds) to Medicines for Malaria Venture, a research institution that focuses on the discovery of new anti-malaria drugs. Three types of promising hit compounds that have the potential to become pharmaceutical products have been identified. In addition, we promoted joint research and from one of these compounds, we acquired two lead compounds as new anti-malaria drug candidates.

Further, following the provision of financial support for the GHIT Fund first phase activities (fiscal 2013 – fiscal 2017), the Company will also provide financial support to the GHIT Fund for second phase activities (fiscal 2018 - fiscal 2022).

# Participating in vaccine support activities

The Group has been participating in vaccine support activities for children in developing countries since 2014. Through this program, unneeded books, CDs and DVDs are donated and the proceeds from their sale are donated to Authorized NPO Japan Committee Vaccines for the World's Children. Through this international contribution activity, those donations are used to deliver vaccines to children in developing countries, such as vaccines for six major infectious diseases. The price of polio vaccine is only ¥20 per person. One book that is sitting on a shelf can save two children from polio.

In fiscal 2018, a total of ¥289,982, equivalent to polio vaccines for 14,500 children, was raised from employee donations and matching gifts from the Company.



Original poster

# Development of science and technology support for research foundations

Mitsubishi Tanabe Pharma provides financial assistance for the activities of research foundations to promote research and provide information in a broad range of fields including medicine, pharmaceuticals, agriculture, and the physical sciences and to thereby contribute to medical treatment and public health.

#### **SENSIN Medical Research Foundation**

This foundation was established in 1968 with support from the former Yoshitomi Pharmaceutical Industries. The foundation aims to contribute to the medical treatment and health of consumers by promoting advanced research in the fields of medicine and pharmacology. In fiscal 2018 the foundation provided 102 grants with a total amount of ¥135.0 million.

# **Japan Foundation for Applied Enzymology**

This foundation was established in 1964 with support from the former Tanabe Seiyaku. The foundation aims to contribute to the development of various fields in the life sciences in Japan by supporting research on enzymes and other molecules affecting the regulation and maintenance of biological functions. In fiscal 2018, the foundation provided 132 grants with a total amount of ¥73.0 million.

# **Environmental Initiatives**











# ■ Environmental management

Based on its Environmental and Safety Policy, the Group works to continually reduce its environmental impact and thereby help protect the global environment and realize a sustainable society by actively promoting resource and energy conservation, waste reduction and other initiatives in all its business activities. In addition, the Group voluntarily engages in environmentally conscious activities, appropriately discloses environmental information and promotes environmental communication on environmental and social contribution activities and other topics.

# Addressing environmental risks

In recent years, climate change has become more apparent and there are growing calls around the world for measures to address climate change risk. In addition, water-related risks, such as water depletion, flooding, and water pollution, are susceptible to the influence of climate change. Moving forward, the Group will track and analyze the relationship between its business activities and climate change risk and water-related risks, and will identify risks that affect business operations and identify available opportunities.

# Receipt of the Excellence Award in the Environmental Report Section of the 22nd Environmental Communication Awards

In February 2019, the Mitsubishi Tanabe Pharma Corporate Report 2018 and CSR Activities Report 2018 received the Excellence Award for the second consecutive year in the Environmental Report Section of the 22nd Environmental Communication Awards, which is sponsored by the Ministry of the Environment and the Global Environmental Forum. This award was presented to MTPC for its ambitious approach to environmentally friendly management and proactive information disclosure; specifically, its description of the results of taking on challenging targets to reduce CO<sub>2</sub> emissions and its extensive and thorough disclosure of CSR-related data.





#### WEB

Refer to the following URL for more details on environmental activities. Key environmental performance indicators have acquired third-party certification in order to raise the reliability of information disclosed to stakeholders.



https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/environment/index.html

# Medium-Term Environmental Action Plan (2016 – 2020): Principal objectives and results in fiscal 2018

The Group has set four priority issues of its environmental activities as the themes of its Medium-Term Environmental Action Plan and continues to reduce its environmental impact. Specifically, as climate change measures, "energy conservation and global warming mitigation" have been positioned as the most important environmental theme.

Area	Medium-Term Action Objectives (2020)	Principal Initiatives and Results in Fiscal 2018
Energy conservation and global warming mitigation	Reduce CO2 emissions (production/research bases, offices) for fiscal 2020 compared to fiscal 2010 Japan: by at least 40% Global: by at least 35% Track supply chain CO2 discharge Appropriately manage fluorocarbons	CO2 emissions Japan: 40% reduction (vs. fiscal 2010) Globai: 32% reduction (vs. fiscal 2010) Scope 3 emissions in categories 1, 2, 3, 4, 5, 6, 7, and 12 were tracked, calculated, and disclosed in the CSR Activities Report Conduct simple regular inspections Amount of fluorocarbon recovered and destroyed: 417kg; amount of leakage: 118kg (350t-C0:eq), and since both are small amounts, government reporting is not required
Reduction of waste, effective use of water resources	<ul> <li>Reduce amount of waste generated and maintain zero emissions (final waste disposal rate of less than 0.5%) (Japan Group)</li> <li>Fulfill the responsibility of a waste discharging enterprise for handling waste correctly and ensuring proper treatment by contractors</li> <li>Water usage volume: Reduce by 15% or more by fiscal 2020 compared to fiscal 2010 both in Japan and overseas (production and research bases)</li> </ul>	Japan: Amount of waste generated by 53% reduction (vs. fiscal 2017) Final waste disposal rate for Japan: 0.59% Advanced manifest digitalization Thorough internal evaluation of waste processing contractors Amount of water used Japan: 45% reduction (vs. fiscal 2010) Global: 46% reduction (vs. fiscal 2010)
Chemical substance emissions reductions	Properly manage chemical substances and continually reduce their discharge into the environment Reduce the discharge of toluene by more than 30% by fiscal 2020 in comparison with fiscal 2010	Chemical substance environmental emissions (air and public waters) in Japan     PRTR-listed substances: 5.1% reduction (vs. fiscal 2017)     VOC (excluding PRTR-listed substances: 4.2% reduction (vs. fiscal 2017)      Emissions of toluene to the environment:     Decrease of 32% (vs. fiscal 2010)
Preservation of biodiversity	<ul> <li>Understand the relationship between business activities and biodiversity and promote biodiversity initiatives</li> </ul>	<ul> <li>Advanced environmental conservation activities, such as planting at Ikoma Mountain (Osaka Prefecture) and natural woodland conservation in the Hachioji Takiyama Area (Tokyo Prefecture)</li> </ul>

# Financial and Non-Financial Highlights

Mitsubishi Tanabe Pharma Corporation and consolidated subsidiaries

			(Billions of yen)	(% Change)
	FY 2016	FY 2017 <sup>1</sup>	FY 2018	FY 2017/2018
Revenue	423.9	433.8	424.7	-2.1
Core operating profit	94.5	78.5	55.8	-28.9
Operating profit	94.0	77.2	50.3	-34.9
Profit attributable to owners of the Company	71.2	57.9	37.3	-35.5
R&D expenses	64.7	79.0	86.5	+9.4
Capital expenditures <sup>2</sup>	14.4	6.0	8.5	+41.7
Total assets	984.5	1,048.4	1,056.2	+0.7
Total equity	871.4	894.8	910.3	+1.7
Net cash provided by operating activities	59.7	66.9	41.4	_
Net cash used in investing activities	-10.5	-19.1	-31.2	-
Net cash used in financing activities	-24.4	-32.5	-25.8	_
			(%)	
Financial indicators				
Overseas revenue ratio	24.4	26.0	27.6	
Operating margin	22.2	17.8	11.8	
R&D expenses ratio	15.3	18.2	20.4	
Ratio of equity attributable to owners of the Company to total assets	87.4	84.2	85.0	
ROE	8.5	6.6	4.2	
Dividend payout ratio	40.9	63.9	84.0	
			(Yen)	(%)
Per share amounts				
Profit attributable to owners of the Company	127.03	103.35	66.64	-35.5
Cash dividends	52.00	66.00 <sup>3</sup>	56.00	_
				(%)
Cost of sales				
Number of employees	7,280	7,187	7,228	+0.6
Number of clinical trials started <sup>4</sup>	4	6	3	_
CO <sub>2</sub> emissions <sup>5</sup> (Thousands of tons-CO <sub>2</sub> )	102	96	91	-5.9
Water Withdrawal (Thousand m³)	7,980	5,375	4,913	-8.6
Waste Generation (Domestic) (t)	5.936	12.230	5.768	-52.8
Final waste disposal rate (Domestic) (%)	0.33	0.37	0.59	_

<sup>1.</sup> MTPC has finalized the purchase price allocation in connection with the acquisition of NeuroDerm Ltd. during the first six months of the fiscal year ending March 31, 2019. Hence, a retroactive adjustment of the comparative amount for previous fiscal year listed in Condensed Consolidated Statements of Financial Position was made.

<sup>2.</sup> Property, plant and equipment and intangible assets on an accrual basis.

<sup>3.</sup> In commemoration of the 10th anniversary of its founding, the Company paid a commemorative dividend of ¥10 per share in fiscal 2017.

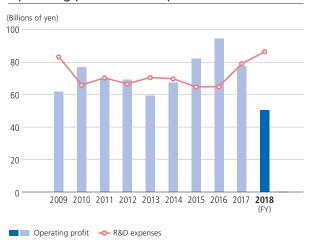
<sup>4.</sup> Phase 2 clinical trials and thereafter. Including in-licensed products.

<sup>5.</sup> Domestic and overseas production and research bases, and offices (the amount of fuel used in sales vehicles is not included in the total).

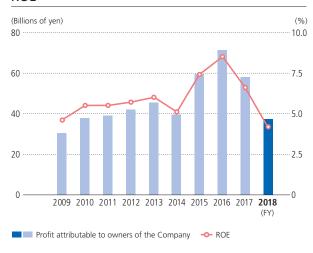
# Revenue / Operating margin



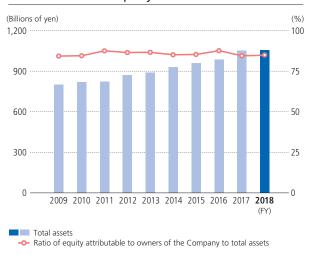
# Operating profit / R&D expenses



# Profit attributable to owners of the Company / ROE



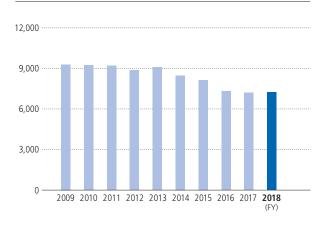
# Total assets / Ratio of equity attributable to owners of the Company to total assets



# Cash dividends per share / Dividend payout ratio



# Number of employees



In commemoration of the 10th anniversary of its founding, the Company implemented a commemorative dividend of ¥10 per share in fiscal 2017.

# Corporate Data / Investor Information

# Corporate data As of March 31, 2019

Company name Mitsubishi Tanabe Pharma Corporation Headquarters 3-2-10, Dosho-machi, Chuo-ku, Osaka

Date of merger Number of employees October 1, 2007 7,228 (Consolidated)

541-8505, Japan

December 1933

4,111 (Parent company only)

Incorporated

For further information

Investor Relations Group Corporate Communications Department

Tel: 81-6-6205-5211 Fax: 81-6-6205-5105 URL: https://www.mt-pharma.co.jp/e/

Group companies As of June 30, 2019 Consolidated subsidiary Affiliated company accounted for by the equity method

### Japan

	Paid-in capital	% Voting control*	Principal business
Yoshitomiyakuhin Corporation	¥385 million	100.0%	Provision of information about pharmaceuticals
Mitsubishi Tanabe Pharma Factory Ltd.	¥1,130 million	100.0%	Manufacture and sale of pharmaceuticals
Mitsubishi Tanabe Pharma Provision Co., Ltd.	¥100 million	100.0%	Operations relating to pharmaceutical information, and operations relating to accounting, general affairs, personnel, etc.
Tanabe Palm Service Co., Ltd.	¥10 million	100.0%(100.0%)	Printing, in-house mail delivery, office support
Stelic Institute & Co., Inc.	¥1 million	100.0%(100.0%)	Pharmaceutical R&D
BIKEN Co., Ltd.	¥100 million	33.4%	Manufacture and sale of biological products including vaccines

# **Overseas**

North America	Paid-in capital	% Voting control*	Principal business
Mitsubishi Tanabe Pharma Holdings America, Inc.	USD 167	100.0%	Management of U.S. business
Mitsubishi Tanabe Pharma Development America, Inc.	USD 200	100.0% (100.0%)	Pharmaceutical R&D
Mitsubishi Tanabe Pharma America, Inc.	USD 100	100.0% (100.0%)	Sale of pharmaceuticals
MP Healthcare Venture Management Inc.	USD 100	100.0% (100.0%)	Investments in bio-ventures
Tanabe Research Laboratories U.S.A., Inc.	USD 3 Mill.	100.0% (100.0%)	Pharmaceutical R&D
Mitsubishi Tanabe Pharma Canada, Inc.	CAD 4 Mill.	100.0% (100.0%)	Sale of pharmaceuticals
MTPC Holdings Canada Inc.	CAD 618.4 Mill.	100.0%	Investments in Medicago Group
Medicago Inc.	CAD 828.0 Mill.	60.0% (58.1%)	Vaccine R&D and manufacture
Medicago USA Inc.	USD 99	60.0% (60.0%)	Manufacture of vaccines
Medicago R&D Inc.	CAD 500	60.0% (60.0%)	Vaccine R&D

Asia	Paid-in capital	% Voting control*	Principal business
Mitsubishi Tanabe Pharma Development (Beijing) Co., Ltd.	USD 1 Mill.		Pharmaceutical R&D
Tianjin Tanabe Seiyaku Co., Ltd.	USD 16.2 Mill.	75.4%	Manufacture and sale of pharmaceuticals
Taiwan Tanabe Seiyaku Co., Ltd.	TWD 90 Mill.	65.0%	Manufacture and sale of pharmaceuticals
Tai Tien Pharmaceuticals Co., Ltd.	TWD 20 Mill.	65.0%	Sale of pharmaceuticals
PT Mitsubishi Tanabe Pharma Indonesia	USD 2.5 Mill.	99.6%	Manufacture and sale of pharmaceuticals
Mitsubishi Tanabe Pharma Singapore Pte. Ltd.	SGD 2 Mill.	100.0%	Management of ASEAN business
Mitsubishi Tanabe Pharma Malaysia Sdn. Bhd.	MYR 5 Mill.	100.0% (100.0%)	Sale of pharmaceuticals
Mitsubishi Tanabe Pharma (Thailand) Co., Ltd.	THB 103 Mill.	100.0% (2.0%)	Sale of pharmaceuticals
Mitsubishi Tanabe Pharma Korea Co., Ltd.	KRW 2,100 Mill.	100.0%	Manufacture and sale of pharmaceuticals

Europe / Middle East	Paid-in capital	% Voting control*	Principal business
NeuroDerm Ltd.	USD 58,000	100.0%	Pharmaceutical R&D
Mitsubishi Tanabe Pharma Europe Ltd.	GBP 4.6 Mill.	100.0%	Pharmaceutical R&D
Mitsubishi Tanabe Pharma GmbH	EUR 25,000	100.0% (100.0%)	Sale of pharmaceuticals

<sup>\*</sup> Figures in parentheses show indirect control.

Note: Aside from the above, The Company owns 5 consolidated subsidiaries. Among them, 2 companies are under liquidation and 1 company is a dormant company. Furthermore, the executive compensation BIP Trust is included as a consolidated subsidiary.

# **Corporate Communications Tools**

To foster a deeper understanding of the Group among stakeholders,
Mitsubishi Tanabe Pharma prepares a variety of communications tools in addition to disclosure materials.

# Providing information about initiatives targeting sustained growth

#### Mitsubishi Tanabe Pharma Corporate Report 2019

Mitsubishi Tanabe Pharma has prepared this integrated report to inform various stakeholders including shareholders and investors about the Group's initiatives targeting sustained growth. In editing this report, we referenced the framework released by the International Integrated Reporting Council (IIRC)<sup>1</sup>. The Value Creation Story introduces our long-term value creation capability in an easy-to understand format, and the Business and Financial Strategy, Non-Financial Information, and Management's Discussion and Analysis sections explain in detail the initiatives and data for each of our businesses that support value creation.

1. Private-sector organization established in 2010 by private-sector companies, investors, accountants' organizations, and government institutions to develop an international corporate reporting framework.



# Providing information about initiatives targeting the sustainable development of society

### **CSR Website (within the Corporate Website)**

Mitsubishi Tanabe Pharma provides information on the CSR website to a wide range of stakeholders, including patients and their families, healthcare professionals, shareholders and investors, local communities, and employees, about the principal CSR activities carried out by MTPC (initiatives targeting the sustainable development of society). This website includes information about specific initiatives based on the corporate philosophy, presented in accordance with the ISO 26000 core subjects. Other sections on the website include the VOICE section, which contains messages from employees and outside parties related to those initiatives, and the data section, which contains related data.



https://www.mt-pharma.co.jp/ shared/show.php?url=../e/ company/csr-report/index.html

# Inclusion in SRI indexes<sup>2</sup> (as of June 2019)

Mitsubishi Tanabe Pharma's initiatives in the area of CSR activities have been highly evaluated, and we have been included in the following SRI indexes.

2. Indicators of socially responsible investment, which utilizes evaluation/selection standards that consider not only corporate financial matters but also social responsibility.



FTSE4Good



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Dow Jones
Sustainability Indices
In Collaboration with RobecoSAM



# Other communications tools

To foster a better understanding of the Group's businesses among a wide range of stakeholders, Mitsubishi Tanabe Pharma has created a corporate website and prepared a corporate profile in pamphlet form.

#### **Corporate Website**

In addition to corporate information, the Group has prepared a variety of specialized sites, such as an investor relations site for shareholders and investors and a health support site.



https://www.mt-pharma.co.jp/e/

#### **Corporate Profile**

The corporate profile is a digest version of Mitsubishi Tanabe Pharma Corporate Report 2019.









